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Attorneys for Defendant
PAR PHARMACEUTICAL, INC.

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

STEPHEN WENDELL and LISA WENDELL, for themselves and as successors in interest to MAX WENDELL, deceased,

Plaintiffs,

vs.

JOHNSON & JOHNSON; CENTOCOR, INC.; ABBOTT LABORATORIES; SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE; TEVA PHARMACEUTICALS USA; GATE PHARMACEUTICALS, a division of TEVA PHARMACEUTICALS USA; PAR PHARMACEUTICAL, INC.,

Defendants.

Case No. 4:09-cv-04124-CW

DEFENDANT PAR PHARMACEUTICAL, INC.'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES

[DECLARATION OF PRENTISS W. HALLENBECK, JR.; AND [PROPOSED] ORDER FILED CONCURRENTLY HEREWITH]

Hearing Date: September 1, 2011

Hearing Time: 2:00 p.m.

Hearing Location: Courtroom 2

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD HEREIN:

NOTICE IS HEREBY GIVEN that, on September 1, 2011, at 2:00 p.m. or as soon thereafter as the matter may be heard in Courtroom 2 of the above-entitled court, located at 1301 Clay Street, Oakland, California, Defendant PAR PHARMACEUTICAL, INC., ("Par") will and hereby does move for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure.

This motion is made on the ground that Plaintiffs STEPHEN WENDELL and LISA WENDELL, for themselves and as successors-in-interest to MAXX WENDELL, deceased ("Plaintiffs") cannot establish proximate cause. Plaintiffs' claims against Par are failure to warn claims, and there is no genuine issue as to any material fact that the prescribing physician did not rely on anything written, published, or disseminated by Par and that the prescribing physician was independently aware of the reported risk Plaintiffs alleged in this action. Plaintiffs therefore cannot establish that Par's allegedly inadequate warnings caused their injuries, and Par should be dismissed from this action.

This motion is based on this notice, the memorandum of points and authorities, the declaration of Prentiss W. Hallenbeck, Jr. (and all attachments thereto, filed herewith), all pleadings and papers on file in this action, and upon such other oral or documentary evidence that may be presented at the hearing.

Respectfully submitted,
HASSARD BONNINGTON LLP

Dated: July 28, 2011

/s/ Kendra J. Pappas
Attorneys for Defendant
Par Pharmaceutical, Inc.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Plaintiffs' Fourth Amended Complaint ("FAC") asserts two causes of action, strict liability and negligence, against Par Pharmaceutical, Inc. ("Par"). As a matter of law, and in keeping with Plaintiffs' allegations, both causes of action are failure to warn claims. Plaintiffs' decedent, Maxx Wendell, was treated for inflammatory bowel disease ("IBD") and died of hepatosplenic T-cell lymphoma ("HSTCL"). One of the medications prescribed for Maxx Wendell, and the product for which Par is alleged by Plaintiffs to be liable, is 6-MP (also known as mercaptopurine and by the brand name Purinethol®). Plaintiffs allege that Maxx Wendell's HSTCL was caused by a failure to warn on the part of Par and the other manufacturers of the products identified in the FAC. Under California law, Plaintiffs must establish that, had Par provided a different warning, Maxx Wendell's treating physician would have made the decision not to prescribe 6-MP for Maxx Wendell. However, the deposition testimony of the prescribing physician, Dr. Edward J. Rich, establishes that he did not rely on any warnings provided by Par in prescribing 6-MP for Maxx Wendell, and that he, Dr. Rich, was aware of the reported risk of HSTCL when he made the decision to prescribe 6-MP for Maxx Wendell. Because Dr. Rich did not rely on Par's warnings and because he was independently aware of the information Plaintiffs allege it was Par's duty to provide, any alleged inadequacy in Par's warning could not be the proximate cause of Plaintiffs' injuries. As a matter of law, Par is entitled to summary judgment.

II. STATEMENT OF FACTS

Dr. Edward J. Rich treated Maxx Wendell for inflammatory bowel disease ("IBD"). Declaration of Prentiss W. Hallenbeck, Jr., in Support of Defendant Par Pharmaceutical, Inc.'s Motion for Summary Judgment, ¶ 2, Ex. 1 (Transcript of Deposition of Dr. Edward J. Rich ("Rich Dep."), 49:25-50:13). Dr. Rich began his treatment of Maxx Wendell in 1998, when Maxx Wendell was 12. *Id.* Initially, Dr. Rich prescribed Prednisone (a steroid) and Asacol (an anti-inflammatory) for Maxx

Wendell. *Id.* at 75:2-12. Dr. Rich added 6-MP to the regimen in July 1999 in the hope of weaning Maxx Wendell off steroids. *Id.* at 81:21-83:10. In July 2002, Dr. Rich added Remicade® to Maxx Wendell's regimen. *Id.* at 147:24-148:16. Maxx Wendell continued on a combination therapy of Remicade® and 6-MP through March 2006, at which time Remicade® was discontinued. *Id.* at 181:10-182:14. In November 2006, Humira® was prescribed for Maxx Wendell in combination with 6-MP. *Id.* at 217:11-20. Maxx Wendell was diagnosed with HSTCL in July 2007. FAC, ¶ 58.

In deciding to prescribe 6-MP for Maxx Wendell, Dr. Rich testified that he relied on information he learned during his fellowship, information from medical articles, information from other professionals in the field of gastroenterology, information he gleaned from meetings, and patient experience. Rich Dep., 274:10-275:1. He did not identify the labeling or warnings for 6-MP as a source of information on which he relied. Dr. Rich does not remember ever reading the label or the PDR entry for 6-MP. *Id.* at 282:2-283:2. In determining dosage when he prescribed 6-MP, the information Dr. Rich relied upon came from other gastroenterologists, patient experience, and medical literature. *Id.* at 280:12-281:19. He has no recollection of ever reading any material about 6-MP written, published, or disseminated by Par. *Id.* at 284:1-5.

Dr. Rich became aware that malignancies, and specifically lymphomas, have been reported for persons using 6-MP during his fellowship, which fellowship predated his treatment of Maxx Wendell. *Id.* at 88:18-90:8. As to the potential risk of developing HSTCL that has been reported with use of the products at issue, including 6-MP, this information came to the attention of Dr. Rich when cases of HSTCL in persons using the product were first reported in the medical literature. *Id.* at 204:21-207:5. He believes this would have been in 2005. *Id.* He testified that he was aware of the literature as it evolved because this is an important part of his practice. *Id.* Dr. Rich incorporated his knowledge of the potential risk of developing HSTCL into his practice, changing his treatment for his patients, including Maxx Wendell, based on

this knowledge. *Id.* at 207:6-208:17; 284:6-285:1. His knowledge is further evidenced by the fact that he communicated the potential risk for developing HSTCL to his patients, including the Wendell family. *Id.* at 209:21-210:12.

III. ARGUMENT

If the moving party can show that there is no genuine issue as to any material fact, then that party is "entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). To support its motion for summary judgment, the moving party may rely on evidence in the record. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). The responding party must show the existence of a disputed material fact, and may not simply show that there is "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). When reasonable minds could not differ as to the import of the evidence, then summary judgment is proper. *See, e.g., Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250-51 (1986). A court "may, and should, [grant summary judgment] as long as whatever is before the district court demonstrates that the standard for the entry of summary judgment, as set forth in Rule 56(c), is satisfied." *Celotex*, 477 U.S. at 323.

Under California law, claims for personal injury from the ingestion of a prescription drug are failure to warn claims. *See, e.g., Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1061 ("comment k would impose liability on a drug manufacturer only if it failed to warn of a defect of which it either knew or should have known"). "A plaintiff asserting causes of action based on a failure to warn must prove . . . that the inadequacy or absence of the warning caused the plaintiff's injury." *Motus v. Pfizer, Inc.*, 196 F.Supp.2d 984, 991 (C.D. Cal. 2001) (*affirmed*, 358 F.3d 659 (9th Cir. 2004)). If it is not genuinely disputable that a physician would not have changed his or her decision to prescribe a drug even if the manufacturer had provided an adequate warning, then the plaintiff cannot prove proximate cause and the manufacturer is entitled to summary judgment. *Id.*

Under California law, warnings for prescription products are directed to

physicians. *See, e.g.*, *Motus*, 358 F.3d at 661. There are at least two independent bases for demonstrating that a plaintiff cannot establish proximate cause in a prescription drug liability action. First, a defendant manufacturer can demonstrate that the prescribing physician did not rely on the warnings provided by the manufacturer in its labeling. *See, e.g.*, *Motus*, 196 F.Supp.2d at 996 ("[B]ecause [the prescribing physician] did not rely on information from [the manufacturer] in making his decision to prescribe [the product at issue] to [Plaintiff's decedent], Plaintiff cannot prove that adequate warnings would have changed [the prescribing physician's] decision to prescribe [the product at issue] to [Plaintiff's decedent]"). Second, a defendant can demonstrate that the prescribing physician was independently aware of the alleged risk at issue when he or she made the decision to prescribe the medication. *See, e.g.*, *Rosburg v. Minnesota Mining & Mfg. Co.* (1986) 181 Cal.App.3d 726, 735 ("[N]o harm could have been caused by failure to warn of a risk already known").

Dr. Rich testified that he relied on information he learned during his fellowship, information from medical articles, information from other professionals in the field of gastroenterology, information he gleaned from meetings, and patient experience when he prescribed 6-MP for Maxx Wendell; that even his dosing regimen for 6-MP was based on information obtained from sources other than the labeling for the product; that he cannot remember ever reading the labeling for 6-MP; and that he does not recall ever reading anything about 6-MP written, published, or disseminated by Par. Reasonable minds cannot differ as to the import of this evidence. Dr. Rich did not rely on the labeling or the warnings for 6-MP when he prescribed 6-MP for Maxx Wendell, and Par is accordingly entitled to summary judgment.

Moreover, Dr. Rich testified that he was made aware of the potential risk of lymphomas reported with use of 6-MP during his training to become a physician; that he was aware of reports of cases of HSTCL when they were first reported in the medical literature; and that he incorporated this knowledge into his practice during the time that he was treating Maxx Wendell. Thus, Dr. Rich was independently aware of

the reported risk about which Plaintiffs allege Par should have warned him and, as a matter of law, Plaintiffs cannot discharge their burden of proving proximate cause. Par is entitled to summary judgment on this basis as well.

IV. CONCLUSION

For the reasons enumerated herein, Par requests the Court grant its Motion for Summary Judgment.

Respectfully submitted,

HASSARD BONNINGTON LLP

Dated: July 28, 2011

/s/ Kendra J. Pappas
Attorneys for Defendant
Par Pharmaceutical, Inc.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who have consented to electronic service are being served with a copy of the attached **DEFENDANT PAR PHARMACEUTICAL, INC.'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES** via the CM/ECF system on **July 28, 2011** or via overnight delivery (Federal Express) to the non-CM/ECF participants listed below.

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I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Date: **July 28, 2011**

Esther Hom